

Dear Friend,

When our children are sick, we give them medicine to make them feel better. But a study published this month in the Journal of the American Medical Association has revealed that 99 percent of the dosing cups that are included with over-the-counter cold remedies are flawed.

As a father, I know that nothing is more important to parents than the health of our children. That's why I'm introducing new legislation, the Protecting Our Kids' Medicine Act, which will make medicine cups and dosing devices easier and safer to use.

The Protecting Our Kids' Medicine Act will require that:

- Dosage delivery devices must be included for all over-the-counter liquid drug products;
- The measuring units marked on the medicine cup and used in the label's directions match (so that labels won't direct parents to give one teaspoon of liquid cold medicine to their child with the provided measuring cup labeled in milliliters);
- The abbreviations on the medicine cup and the label's directions match (so that labels don't tell parents to give one "mL" of liquid cold medicine to their child with a provided measuring cup that uses the abbreviation "ml" or "mil");
- Any decimals or fractions listed on the dosage delivery device must be listed as clearly as possible;
- Dosage delivery devices may not bear confusing, unnecessary markings; and

Dangerous Dosage?

Wednesday, December 22, 2010

- The markings on medicine cups and other dosing devices must be clearly visible and cannot be obscured when the liquid medicine is added to the medicine cup.

When your child is sick, you want to make them well as quickly as possible – not accidentally overexpose them to potentially harmful medicines. The Protecting Our Kids' Medicine Act will make dosing cold and cough medicine safer and easier for both parents and kids.

Below, please find a recent Newsday article about my efforts. And for more information on the Protecting Our Kids' Medicine Act, please visit my website at <http://israel.house.gov>.

Sincerely,

Steve Israel

Member of Congress

Newsday: Standard sought for kids' medicine cup

BYLINE: BY DELTHIA RICKS

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A majority of medicine cups accompanying children's over-the-counter medications are flawed and fail to match dosing instructions on the labels, said Rep. Steve Israel, who yesterday

announced new legislation that would standardize dosing devices and simplify the instructions.

With a bag full of brand-name medications - a fraction of those affected - Israel said he's introducing legislation that would require the U.S. Food and Drug Administration to bolster safety, and thus make it easier to give medications to children.

Citing a statistic reported earlier this month in the Journal of the American Medical Association, Israel said 99 percent of medicine cups and dosing devices attached to children's medications are flawed. The cup may clearly mark teaspoons, but dosage instructions on the label may call for tablespoons, he said.

Also, printed instructions are so small and confusing they are difficult to understand, Israel said. "You have to be a NASA engineer with the eyesight of a hawk to read and understand the fine print," said Israel, who called for clear instructions in plain language to avoid potentially dangerous overdoses.

Israel said that as the nation's regulatory agency for drugs, the FDA is chartered to guard the health of people of all ages by requiring companies to provide clear dosing information and easy-to-use dosing devices - but "for 35 years the FDA has been inconsistent on medicine cup inconsistencies."

FDA officials could not be reached last night for comment.

Dr. Michael Grosso, senior vice president of medical affairs at Huntington Hospital and a practicing pediatrician, sees the dosing cup issue as just one aspect of several larger concerns.

"This is a two-part problem," Grosso said. "The first part is that most of the cold and cough medications have limited efficacy in children. The other problem is what Mr. Israel is alluding to, because we've known over a long period of time that parents have problems" with dosing.

Children's over-the-counter drugs have been plagued with problems for years. Earlier this year, many were recalled for contamination. In 2007, an FDA panel of outside experts cited seizures, hallucinations and heart-rate problems among children who received inappropriate dosages of cough and cold remedies.

Federal investigators estimate parents give children 4 billion doses of over-the-counter drugs annually. Israel told a news conference at Huntington Hospital that dosing problems are exacerbated by dosing devices themselves: One-fourth, he said, lack necessary markings, and 80 percent have extraneous dosage markings that have nothing to do with administering the medication. Both can cause medication errors.

Northport mother Kirsten Rasmussen said she has had fears of giving too much medication to her son Jesse, 3, because of dosing cup problems. "I don't think, technically, I overdosed him," she said, and also highlighted differences between dosing devices and instructions.